

Remarks

Entry of the foregoing amendment and reconsideration of the claims is requested. Claims 1, 2, 50-58 and 60 are pending. Each claim amendment makes only minor, formal changes.

The specification has also been amended to insert the meaning of various acronyms (FACS, BODIPY, FCS). The acronyms are well known terms of art that any practitioner of ordinary skill in the art would have understood. Spelling out the acronyms does not constitute an introduction of new matter. The remaining specification amendments make only minor, formal changes.

No new matter has been added to the application.

Telephone Interview of July 12, 2006. Applicants thank the examiner and his supervisor, Jon Weber, for conducting a telephone interview with the undersigned. During the interview it was agreed that the rejection of claim 1 for alleged indefiniteness and the rejection of claim 2 for alleged lack of enablement would be withdrawn.

Objections to the specification. The specification has been objected to because the terms "FACS", "BODIP", "EGFP", "FLAG" and "FCS" have not been spelled out at their first occurrence. The amended specification spells each of the terms at their first occurrence. No amendment was made, however, to spell out the meaning of "EGFP" since it is defined in the specification as filed at page 43, lines 6-7. Furthermore, no amendment was made to spell out the meaning of "FLAG" and no such amendment should be required. FLAG is a term of art that any practitioner of ordinary skill in the art would understand. Moreover, FLAG is a polypeptide whose amino acid sequence is described in the specification at page 43, line 25 (see also SEQ ID NO: 37).

The specification has been objected to because "SEQ ID NO 1", at page 42, lines 18-19, should, according to the examiner, be "SEQ ID NO: 1". The amended specification recites "SEQ ID NO: 1" at this point.

The specification has been objected to because "SEQ ID NO: 39-42" at page 45, line 21, should be, according to the examiner, "SEQ ID NOs: 39-42". The amended specification recites "SEQ ID NOs: 39-42" at this point.

The specification has been objected to because of the occurrence of a series of asterisks (*) at page 61, line 16. The amended specification does not include the asterisks.

Withdrawal of all objections to the specification is requested.

Claim Rejections Under 35 U.S.C. § 112(¶2). Claim 1 stands rejected for allegedly being indefinite due to the lack of functional language indicating that the protein is capable of cholesterol binding. Applicants disagree.

The standard for compliance with 35 U.S.C. § 112(¶2) is that the claim set forth the claimed subject matter and particularly point out and distinctly define the metes and bounds of the claimed subject matter. Claim 1 clearly states that the claimed subject matter covers an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 4. As discussed in the telephone interview, the claimed polypeptides include those that bind cholesterol and those that do not; hence, the claim is compliant and incorporation of this element into the claim would not be appropriate. As agreed to during the interview, this rejection should be withdrawn; such action is requested.

Claim 50 stands rejected for allegedly being indefinite because the phrase "comprising a polypeptide selected from" is unclear because it is unclear to what polypeptide, in the fusion, the claim is referring. Amended claim 50 specifies

that the "other polypeptide" in claim 2 can be any of the recited proteins. Antecedent basis, in claim 2, for the term "other peptide" is the term "another peptide". Withdrawal of the rejection of claim 50, for indefiniteness, is requested.

Claim Rejections Under 35 U.S.C. § 112(¶1). Claim 2 stands rejected for allegedly lacking enabling disclosure in the specification. The examiner took the position that there is no guidance in the specification defining how to fuse the polypeptide comprising SEQ ID NO: 4 to another polypeptide while retaining its biological activity. As discussed during the telephone interview, the claim is enabled since there is no absolute requirement for the fused polypeptide to retain biological activity. Even fusions which lack biological activity are useful. For example, a biologically inactive polypeptide comprising the amino acid sequence of SEQ ID NO: 4 can be used as an antigen for the generation of an antibody.

As agreed to during the interview, this claim rejection should be withdrawn; such action is requested.

Conclusion:

The claims are in condition for passage to allowance.
Such action is earnestly solicited.

Respectfully submitted,

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